

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Robert Alpern, et al.

Group Art Unit: 1614

Serial Number: 10/814,527

Examiner: Ardin H. Marschel

Filing Date: March 30, 2004

CONFIRMATION NO: 6886

Title: METHODS AND COMPOSITIONS FOR
TREATMENT OF ION IMBALANCES

FILED ELECTRONICALLY ON: AUGUST 7, 2006

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.97

Sir:

Applicant(s) hereby submit(s) an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

Applicant(s) respectfully request(s) that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicant(s) further request(s) that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

- A. ☒ 37 CFR §1.97(b). This Information Disclosure Statement should be considered by the Office because:
- ☐ (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under §1.53(d);
-- OR --
 - ☐ (2) It is being filed within 3 months of entry of the national stage as set forth in §1.491 in an international application;
-- OR --
 - ☒ (3) It is being filed before the mailing of a first Office action on the merits;
-- OR --
 - ☐ (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- B. ☐ 37 CFR §1.97(c). Although this Information Disclosure Statement is being filed after the period specified in 37 CFR §1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:
- ☐ a statement as specified in §1.97(e) provided concurrently herewith;
-- OR --
 - ☐ a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- C. ☐ 37 CFR §1.97(d). Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:
- i. a statement as specified in §1.97(e);
-- AND --
 - ii. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.
- D. ☐ 37 CFR §1.97(e). Statement.
- ☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(c);
-- AND/OR --
 - ☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(d);
-- AND/OR --
 - ☐ A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e)(1) as provided for under MPEP 609.04(b) V.
- E. ☐ Statement Under 37 C.F.R. §1.704(d). Each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart application that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the

requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.

F. ☒ 37 CFR §1.98(a)(2). The content of the Information Disclosure Statement is as follows:

☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

-- OR --

☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are NOT enclosed.

-- AND/OR --

☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2).

-- AND/OR --

☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).

G. ☐ 37 CFR §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.

☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

☐ Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

☐ A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: _____

☐ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

H. ☐ 37 CFR §1.98(d). Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

☐ Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.

Application in which the information was submitted: _____

Information Disclosure Statement(s) filed on: _____

AND

☐ The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.


- I. ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 29329-714.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: August 7, 2006

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 56631

By: 
Anie K. Roche, Reg. No. 50,512

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| | | | | Application Number | 10/814,527 |
| | | | | Filing Date | March 30, 2004 |
| | | | | First Named Inventor | Robert Alpern |
| | | | | Art Unit | 1614 |
| | | | | Examiner Name | Ardin H. Marschel |
| Sheet | 1 | Of | 2 | Attorney Docket Number | 29329-714.201 |

| U.S. PATENT DOCUMENTS | | | | | | |
|--------------------------|-----------------------|--|--------------------------------|--|---|----------------|
| Examiner Initials* | Cite No. ¹ | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | |
| /N.L./ | 5. | US 3,499,960 | 03-10-1970 | Macek et al. | | |
| /N.L./ | 6. | US 5,487,888 | 01-30-1996 | Mandeville, III et al. | | |
| /N.L./ | 7. | US 5,702,696 | 12-30-1997 | Mandeville, III et al. | | |
| FOREIGN PATENT DOCUMENTS | | | | | | |
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document Country Code ³ - Number ⁴ - Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| /N.L./ | 8. | WO 2005/065291 A2 | 07-21-2005 | Genzyme Corporation | | |
| /N.L./ | 9. | WO 02/12160 A1 | 02-14-2002 | Solvay | | |

/Neil Levy/ (10/19/2010)

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|--------------------|--------------------------|-----------------|--|
| Examiner Signature | /Neil Levy/ (10/19/2010) | Date Considered | |
|--------------------|--------------------------|-----------------|--|

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| | | | | First Named Inventor | Robert Alpern |
| | | | | Art Unit | 1614 |
| | | | | Examiner Name | Ardin H. Marschel |
| Sheet | 2 | Of | 2 | Attorney Docket Number | 29329-714.201 |

| NON PATENT LITERATURE DOCUMENTS | | | | |
|---------------------------------|-----------------------|---|--|--|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | |
| /N.L./ | 10. | Coli, L. et al. 1992. Phosphate Removal by Resin Hemoperfusion Efficacy and Biocompatibility of a New Exchange Resin. <i>Biomaterials, Artificial Cells, and Immobilization Biotechnology</i> . 20(5): 1153-1163. | | |
| /N.L./ | 11. | Forrest, M. Laird, et al. 2003. A Degradable Polyethylenimine Derivative with Low Toxicity for Highly Efficient Gene Delivery. <i>Bioconjugate Chem.</i> 14(5): 934-940. | | |
| /N.L./ | 12. | Koping-Hoggard, M. et al. 2001. Chitosan as a nonviral gene delivery system. Structure-property relationships and characteristics compared with polyethylenimine in vitro and after lung administration in vivo. <i>Gene Therapy</i> . 8: 1108-1121. | | |
| /N.L./ | 13. | Thomas, Mini, et al. 2005. Cross-linked Small Polyethylenimines: While Still Nontoxic, Deliver DNA Efficiently to Mammalian Cells in Vitro and in Vivo. <i>Pharmaceutical Research</i> . 22(3): 373-380. | | |

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|--------------------|--------------------------|-----------------|--|
| Examiner Signature | /Neil Levy/ (10/19/2010) | Date Considered | |
|--------------------|--------------------------|-----------------|--|

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